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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,981	BEHNAM ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *1-30,47 and 49-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-46 and 48* is/are rejected.

7)☒ Claim(s) *43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060629, 20071015, 20091015*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, claims 31-46 and 48, in the reply filed on 7/17/2009 is acknowledged. Claims 1-72 remain pending in the instant application, of which claims 1-30, 47 and 49-72 are withdrawn from consideration as being directed to non-elected inventions, pursuant to 37 CFR 1.142(b). Claims 31-46 and 48 have been considered on the merits.

Priority

The instant application is acknowledged to be a national stage entry under 35 USC 371, of international application PCT/US04/43999, filed 12/31/2004, and which further claims priority to US provisional application 60/533,537, filed 12/31/2003.

Drawings

The drawings are objected to because Figure 5 fails to uniquely identify Figures 5a, 5b and 5c as referenced in the specification under "Brief Description of the Drawings" at Pg. 9 of the specification (three visuals are provided, but they are not labeled "a," "b," or "c"). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 43 is objected to for a minor informality: Claim 43 does not end with a period (".") Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-36, 43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "the marker is alkaline phosphatase", however claim 33 depends from claim 31, which does not recite a marker and thus there is insufficient antecedent basis for this limitation in the claim. It appears claim 33 should depend from claim 32. Examination has been conducted as such, yet correction is required.

Each of claims 34-36 are directed to the modified bone matrix of claim 31 and further state the expression of "the marker" is varied in comparison to the expression of "the marker" induced by a different treatment agent; there is insufficient antecedent basis for the limitation "the marker" in any of

claims 34-36. It is unclear if claims 34-36 are intended to depend from claim 32 or 33, or from another claim. Clarification is required.

Furthermore, in each of claims 34-36, it is unclear what the expression level of 'the marker' is being compared to, for example, claim 34 requires the expression of the marker to be within a factor of 2 relative to that induced by BMP-2; does this mean the expression level of the marker within the modified bone matrix composition is within a factor of 2 of the expression level of the marker within a control bone matrix which was contacted with BMP-2? It is not clear what is being 'induced by BMP-2? In claim 35 it is unclear what is being induced by 10% fetal bovine serum. In claim 36 it is unclear what is being induced by an inactivated bone matrix. No discernible meaning can be gleaned from claims 34-36.

Claim 43 recites the limitation "the unmodified bone matrix" in the second line of the claim; there is insufficient antecedent basis for this limitation in the claim. Claim 31 does not recite an unmodified bone matrix. Correction is required.

Claim 45 recites the modified bone matrix has osteoinductive activity in 'a species' in which the unmodified bone matrix is not osteoinductive. The claim language does not provide sufficient context for the term 'species', thus it cannot be determined from claim 45 whether the 'species' is that of animal, chemical, etc. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 38-42 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Leary et al (US Patent 5,236,456).

O'Leary et al discloses an osteogenic composition comprising demineralized bone matrix which has been subjected to an acid treatment and then heated; the resulting composition is described as a liquid surface-adherent osteogenic composition (See O'Leary et al, col. 2, ln 14-29).

The acid/heat treatment changes the physical state of the bone matrix to a liquid composition which has increased surface-adherent capability compared to the solid-state matrix (See O'Leary et al, col. 2, ln 35-40 & claim 1). Surface-adherent capability, per se, is considered a 'biological activity', however, O'Leary et al further state that the increased surface-adherent capability increase the osteoinductivity of the osteogenic composition, as the improved adherence to the bone defect site is reported to improve the osteoinductive activity of the composition (See O'Leary et al, again, col. 2, ln 35-40); thus the acid/heat treated, surface-adherent osteogenic composition of O'Leary et al reads on the modified bone matrix of claims 31, 38, 39 and 40.

O'Leary et al further report demineralized bone powder, bone morphogenic proteins, antibiotics, cells, polynucleotides, collagen, and vitamins may further be combined with the acid/heat treated, surface-adherent osteogenic composition (modified bone matrix) (See O'Leary et al, col. 2, ln 65-col. 3, ln 5 & claims 11, 12, 23-25); bone morphogenic proteins read on at least small molecules, chemical compounds, proteins, protein fragments, peptides, growth factors and drugs, antibiotics read on

antibiotics, as well as drugs and chemical compounds, cells read on cells, and also contain polynucleotides, proteins, protein fragments and peptides (claim 41).

O'Leary et al further reports the inorganic components of the liquid surface-adherent osteogenic composition can be precipitated out, lyophilized into a powder, and the powder reconstituted in aqueous solvents, such as acetic acid or HCl, to form an aqueous solution, comprising the modified bone matrix and the carriers, suitable for injection into tissue (See O'Leary et al, col. 5, ln 49-col. 6, ln 18); the aqueous solvents, such as acetic acid or HCl, are considered to read on carriers which may be combined with the osteogenic composition (modified bone matrix composition) (claim 42).

Finally, O'Leary et al further teaches the liquid surface-adherent osteogenic composition (modified bone matrix) can be combined with a surgical implant, such as donor bone tissue, an osteoprosthetic device, an orthopedic fracture wrapping and a collagen-coated microspherical filler (See O'Leary et al, col. 7, ln 34-50); each of the recited surgical implants are considered to read on 'components', and the combination of the surgical implant and the osteogenic composition is considered to read on a device for bone repair comprising the acid/heat treated, surface-adherent osteogenic composition (modified bone matrix of claim 31) and an additional component, having a shape suitable for implantation (claim 48).

Therefore the reference anticipates the claimed subject matter.

Claims 31-36, 38-40, 43-46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Landesman et al (Calcified Tissue International, 1989).

Landesman et al disclose demineralized bone matrix which has been subjected to collagenase treatment (See Landesman et al, Pg. 349, Materials and Methods: "Preparation of Demineralized Bone Matrix" and "Enzymatic Treatment of Bone Matrix").

The method of Landesman et al (involving demineralization of bone matrix and then partial digestion with collagenase) is identical to the method reported in the instant disclosure to yield the currently claimed modified demineralized bone matrix having a level of at least one biological activity being increased relative to its level in a control (i.e. non-collagenase treated) demineralized bone matrix (See specification, Example 10, Fig. 3 and Fig. 6).

It has been held that where the claimed and prior art products are identical in structure or composition, or are produced by identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, because the collagenase-treated demineralized bone matrix of Landesman et al is produced by the same method as taught in the instant disclosure, the collagenase-treated demineralized bone matrix of Landesman et al is considered to be inherently identical to the modified bone matrix of claims 31, 39 and 40, as well as the device for bone repair of claim 48 (noting claim 48 does not require anything more than the treated demineralized bone matrix, per se).

Furthermore, it has been held that "[P]roducts of identical chemical composition can not have mutually exclusive properties." A chemical composition (or in the instant case the collagenase-treated demineralized bone matrix) and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure (i.e. the collagenase-treated demineralized bone matrix), the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the properties recited by claims 31-36 and 43-46 are inherent to the collagenase-treated demineralized bone matrix of Landesman et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of O'Leary et al US Patent 5,236,456) and Landesman et al (Calcified Tissue International, 1989).

The teachings of each of O'Leary et al and Landesman et al are set forth above. Each of O'Leary et al and Landesman et al have been shown to anticipate at least the modified bone matrix of claim 31. O'Leary et al and Landesman et al differs from the modified bone matrix of claim 37 in that neither reference specifies the bone material to be treated may be derived from humans.

However, it is submitted that one having ordinary skill in the art would have found it *prima facie* obvious to utilize human bone as the bone source for the subsequent treatments of each of O'Leary et al and Landesman et al in order to provide a final product which would be autologous, or at least allogeneic, to human recipients. In the field of bone substitute materials, it is clearly an ultimate objective to develop bone substitute materials which may be used in human patients in need thereof; the artisan of ordinary skill will recognize that when autologous bone material (the gold standard) is unavailable the next best option is allogeneic bone material, i.e. derived from a human. Therefore, it would have been *prima facie*

obvious to employ the techniques taught by each of O'Leary et al and/or Landesman et al on donor human bone.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31, 38-40, 42, 43 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 73, 77, 83 and 84 of copending Application No. 12/140,025 (hereafter application '025). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims of application '025 anticipate the subject matter.

The osteoinductive composition of copending claim 73 is an at least partially demineralized bone which has been treated to increase the osteoinductive activity of the bone as compared to untreated demineralized bone matrix. The increase in osteoinductive activity reads on an increase in biological activity, as required by claim 31, and specifically on an increase in osteoinductive activity, as required by claim 38. The osteoinductive composition comprises at least partially demineralized bone matrix, which

reads on the at least partially demineralized bone matrix and at least partially demineralized bone section of claims 39 and 40, respectively.

Copending claim 77 states the osteoinductive composition has increased solubility as compared to untreated demineralized bone matrix, thereby anticipating instant claim 43.

Copending claim 83 states the osteoinductive composition is formed into an implant, which reads on a device comprising the osteoinductive composition (which reads on the modified bone matrix of claim 31), thereby anticipating claim 48.

Copending claim 84 states the osteoinductive composition may further comprise a carrier, thereby anticipating instant claim 42.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651